UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,627	06/20/2005	Kiyoshi Ando	09617.0001	4183

22852 7590 03/06/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
03/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,627	ANDO ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9 and 21-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7-9 and 21-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/12/07 is acknowledged.

Claims 1, 7-9 and 21-41 are pending.

Claims 1, 7-9 and 21-41 read on a method for diagnosing leukemia, pre-leukemia or aleukemic malignamt blood disease, wherein stem cells growth factor (SCGF) is quantified are under consideration in the instant application.

The following new grounds of rejections are necessitated by the amendment, filed on 12/12//07.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 28 are indefinite in the recitation of antibody KM2142 and KM2804 and hybridoma FERM BP-7923 or FERM BP-7922 because its characteristics are not known. The use of " KM2142 and KM2804 " monoclonal antibody and hybridoma FERM BP-7923 or FERM BP-7922 as the sole means of identifying the claimed antibody and hybridoma renders the claim indefinite because KM2142 and KM2804 and hybridoma FERM BP-7923 or FERM BP-7922 " is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct hybridomas or monoclonal antibody.

Applicant should amend the claims to provide deposit accession number or other means of distinctly claiming the referenced antibody.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 7-9 and 21-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing ALL, AML, CML, MDS, NHL or MM diseases comprising method steps as recited in claim 1, does not reasonably provide **enablement** for a method for diagnosing any leukemia, pre-leukemia or aleukemic malignant blood diseases comprising method steps recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

The specification only discloses a detailed examples of construction and characterization of polyclonal and monoclonal antibody for SCGF (See entire document, Examples 1-6 in particular). The Specification also disclosed that said antibodies have been used to detect the level of SCGF in serum of healthy individuals and in patients with ALL, AML, CML,MDS NHL or MM and AA (see overlapping pages 57-59 and Fig.7 in particular). The Specification disclosed that a statistically significant elevated levels in the serum SCGF levels have been detected only in patients with very specific diseases, i.e. ALL, AML, CML,MDS NHL or MM compare to healthy individuals.

However, it is noted that the specification disclosed that "in general the distribution of the measured values of a disease group of the interested **partially overlaps those of the non-disease group**" . (see overlapping pages 12 and 13 in particular). Moreover, the specification disclosed that there were patient that were diagnosed as being disease negative in spite of being a disease patients (see page 12 in particular). The Specification further disclosed that no significant differences was observed between the values of SCGF for patients of aplastic anemia (AA) and health individuals (see page 58 in particular). In other words, the Specification provides no data that there is a correlation between the levels of serum SCGF and predictability for diagnosing any leukemia, pre-leukemia or aleukemic malignant blood diseases. Moreover, it is noted that the is no recognition in the prior art that the levels of SCGF in serum of the patients can serve as an indicative of leukemia, pre-leukemia or aleukemic malignant blood disease. Thus, in the absence in the instant Specification and in the prior art evidences allowing one skill in the art to correlate the levels of SCGF in the serum of the patients and predisposal of said patients to leukemia, pre-leukemia or aleukemic malignant blood diseases, the intended method for diagnosing said diseases by measuring the levels of SCGF are fraught with uncertainties.

The specification does not provide sufficient teaching as to how it can be assessed that a patient has leukemia , pre-leukemia or aleukemic malignant blood disease by quantifying the levels of SCGP. Thus, the specification describes the means of measuring the levels of SCGF in the serum of patient, and the statistically significant difference in the serum SCGF levels in patients with very specific diseases, i.e. ALL, AML, CML,MDS NHL or MM compare to healthy individuals. However, there is no correlation on this record between the levels of said growth factor and a proposed method for diagnosing any leukemia, pre-leukemia or aleukemic malignant blood diseases in currently available form for humans or animals. It is not enough to rely on *in vivo* studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to efficacy in humans or animals (emphasis added). Ex parte Maas, 9 USPQ2d 1746.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method for diagnosing any leukemia, pre-leukemia or aleukemic malignant blood disease by measuring the levels of SCGF in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Also an issue is that claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. In claims 27 and 28 it is apparent that the monoclonal antibody KM2142 and KM2804 are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

It is noted that the specification on page 21 indicates that said antibodies have been deposited with National Institute of Advanced Industrial Science and Technology, Ibaraki.

If the deposit have been made under the terms of the Budapest treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the **plasmid** has been deposited under the Budapest Treaty and that the **plasmid** will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808.

If the deposit has not been made under the Budapest treaty, then an affidevit or declaration by Applicants or someone associated with the patent owner who is in position to make such assurances, or statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met

Amendment of the specification to disclose the date of the deposit and complete name and address of the depository is required

8. No claim is allowed

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571/ 272-0878.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644